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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/872,310	05/31/2001	Robert Ainsworth	3764.P180	4544

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EXAMINER

LIN, JEYUHU

ART UNIT	PAPER NUMBER
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3737

DATE MAILED: 12/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/872,310

Applicant(s)

AINSWORTH ET AL.

Examiner

Jeoyuh Lin

Art Unit

3737

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 September 2003.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Entry of Amendment

1. Applicant's amendment, filed on September 8, 2003, as paper No. 9, is acknowledged. Claims 1-39 are currently pending.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

-Claims 1-6, 8, 9, 11-13, 15-19, 21-24, 26, 28, 32 and 34 are rejected under 35 U.S.C. 102(b) as being anticipated by Kittrell et al. (US 5,693, 043)

Kittrell teaches an apparatus comprising the following:

-An intravascular device to perform a therapeutic treatment, with at least one optical fiber disposed through the intravascular device, the optical fiber configured to provide diagnostic information before and after the therapeutic treatment. (Column 8, lines 53-68, column 19, lines 55-60, and column 23, lines 60-67)

-Wherein the optical fiber is exposed within a vasculature of a patient at least at one location along the intravascular device, as in claim 2. (Column 5, lines 55-67)

-The apparatus of claim 2 wherein the optical fiber is configured to sense vessel and blood characteristics, such as detecting atherosclerotic lesion, as in claim 3. (Column 18, lines 25-30)

-Wherein the intravascular device is a balloon catheter comprising a catheter shaft having an elongated outer member disposed about a tubular inner member, the tubular inner member

having a lumen to receive the optical fiber therethrough, and a balloon coupled to a distal portion of the catheter shaft, as in claim 5 and 22-24. (Column 16, lines 12-30)

-Tubular inner member coupled to the optic fiber, as in 6. (Figure 1)

-Wherein the lumen is to receive an inflation medium therethrough to inflate the balloon, as in 8, 16. (Column 16, lines 10-30)

-Wherein a distal tip of the optical fiber is exposed within a vasculature of a patient at least at one location along the balloon catheter, as in 9.

-Wherein the tubular inner member has a second lumen extending at least within a distal portion of the tubular inner member, the second lumen being substantially parallel to the lumen having the optical fiber therethrough, as in 11 and 17. (Figure 14)

-Wherein the second lumen is a lumen selected from the group consisting of guidewire lumen, inflation lumen, radiation source lumen, drug delivery lumen, artherectomy device lumen and laparoscopy lumen, as in 12 and 18. (Figure 15)

-Wherein a distal tip of the optical fiber is exposed within a vasculature of a patient at least at one location along the balloon catheter, as in 13 and 19. (Figure 13 I and 18)

-Wherein an elongated outer member is disposed about a tubular inner member and an intraluminal gap extending longitudinally between the outer member and the inner member, with at least one optical fiber disposed within the intraluminal gap, the catheter capable of both diagnostic and therapeutic purposes, as in 15. (Figure 1)

-A data processing system; and an apparatus coupled to the data processing system, the apparatus comprising an intravascular device to perform a therapeutic treatment and at least one optical fiber disposed therethrough, the optical fiber configured to provide diagnostic

information before and after the therapeutic treatment, as in 32. (Column 22, lines 57-67)

-Claims 15, 21, and 28-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Gunderson (US 5,601,087)

-Gunderson teaches guidewire for diagnosing tissue, comprising an outer member catheter shaft about a tubular inner member, with optical fiber disclosed within, with the catheter capable of both diagnostic and therapeutic purposes. (Column 5, lines 18-67)

-Radiopaque substance, as in claim 21. (Column 6, lines 60-67)

-Elongated coil, as in 29. (Column 5, lines 48-60)

-Gunderson fails to teach a braided member as an elongated member, as in claim 30.

However, it is well known in the art of guidewire structures that the guidewire can have a braided structure.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

-Claims 4, 10, 14, 20, 25, 27, 31, 33, and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kittrell as applied to claims 1, 15, 22, 26, 28, 32, and 34 above, and further in view of Jackson (US 6,498,941 B1).

Kittrell meets all the claims except that it fails to teach the following:

wherein vessel and blood characteristics are selected from the group consisting of hemodynamic characteristics, hematological parameters related to blood and blood components and thermal parameters of the vasculature.

Jackson teaches a catheter based probe with optical fibers that detect chemical analytes in blood. (Column 2, lines 32-60) It would have been obvious to one having ordinary skill in the art at the time the invention was made to adapt Jackson's teachings to Kittrell's device such that diseased parts of the vasculature that contains artherosclerotic plaque could be detected.

-Claim 1, 5, 7, and 36-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chornenky et al., (US 5,582,171) and in view of Swanson et al. (6,445,939 B1)

Chornenky teaches an intravascular device performing a therapeutic treatment, and at least one optical fiber disposed through the intravascular device, with the optical fiber configured to provide diagnostic information in the form of images before and after therapeutic treatment, and usable for angioplasty procedures, which inherently would involve the use of expandable balloons. (Column 5, lines 8-13 & Column 13, lines 65-67) However, it fails to teach rotating a fiber optic. Swanson teaches a catheter that could be adapted for stent-deployment use, (Column 14, lines 24-26) comprising the rotation of a fiber optic. (Column 13, lines 40-45) It would have been obvious to one having ordinary skill in the art at the time the invention was made to adapt Swanson's teaching to Chornenky's device such that the size of the catheter decreased, while still allowing the diagnostic catheter to obtain information all around the vasculature.

Response to Arguments

4. Applicant's arguments with respect to claims 1-39 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

5. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

-Glass et al. (US 5,938,595) teaches a fiber optic biosensor, comprising the diagnosis of fibrinolytic product in the blood, both before and after therapy.

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeoyuh Lin whose telephone number is (703) 306-5990. The examiner can normally be reached on m-f, 8:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dennis Ruhl can be reached on (703) 308-2262. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-0758.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

JYL

JYL
November 27, 2003

Eleni Mantis Mercader
ELENI MANTIS MERCADER
PRIMARY EXAMINER
ART UNIT 3737